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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,703	02/05/2004	William M. Colone	297912002103	5606

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EXAMINER

AUGHENBAUGH, WALTER

ART UNIT	PAPER NUMBER
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1772

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/772,703

Applicant(s)

COLONE, WILLIAM M.

Examiner

Walter B. Aughenbaugh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-53 is/are rejected.
- 7) ☒ Claim(s) 50 and 53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 28, 2005 (Amdt. A) has been entered.

Acknowledgement of Applicant's Amendments

2. The amendments made in claims 42, 44 and 45 in the Amendment filed November 28, 2005 (Amdt. A) have been received and considered by Examiner.
3. New claims 47-53 presented in Amdt. A have been received and considered by Examiner.

Specification

4. The amendment filed November 28, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the recitation "greater than the original inner diameter" of new claim 50, and the ranges claimed in claims 52 and 53 are not disclosed in the specification as originally filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

5. Claim 50 is objected to because of the following informalities: "PTFE" should be spelled out in full. Appropriate correction is required.

6. Claim 53 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 53 fails to further limit the subject matter of claim 52 because the range "about 6 mm to about 30 mm" lies outside of the range "about 3 mm to about 6 mm" of claim 52.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 42 and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Pmax, as defined on pages 7-8 of the specification, cannot be determined on a balloon that has burst before reaching its Pmax; therefore, the specification does not disclose the calculation of radial expansion ratio, in instances where it is calculated as 1.0, in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed tube having a radial expansion ratio of 1.0.

The specification defines Pmax as the highest pressure at which “the tube retains its structural integrity” which is highest pressure at which the “tube requires the application of an increased inflation pressure before the amount of radial expansion of the tube increases” (page 7, line 32-page 8, line 1). However, once a tube has burst, it cannot be shown that the highest pressure at which the “tube requires the application of an increased inflation pressure before the amount of radial expansion of the tube increases” is the burst pressure because Applicant does not identify bursting as a loss of structural integrity in the definition of “structural integrity” at lines 32-35 of page 7 of the specification (a tube that has burst can still have structural integrity as “structural integrity” is defined in the specification). Therefore, Applicant’s assignment of Pmax as the same pressure as the burst pressure (for example, in Table XI on page 17) is inconsistent with Applicant’s definition of Pmax, as defined on pages 7-8 of the specification.

9. Claims 42, 50, 52 and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In regard to claim 42, the recitation “at least two times said original inner diameter” is not supported in the specification for instances where the radial expansion ratio is 1.0. Tables XI, XII and XVII (pages 7, 19 and 25) show data for tubes with a radial expansion ratio of 1.0, but the % dilation at the bursting pressure is 294, 275 and 252%, respectively. Therefore, the range of

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expansion of from 2.0-2.5 within the claimed range of “at least two times” is not supported since the specification does not provide support for a tube that has a radial expansion ratio of 1.0 that is expanded less than 2.5 times its original inner diameter.

In regard to claim 50, the recitation “greater than the original inner diameter” is not supported in the specification for instances where the radial expansion ratio is 1.0. Tables XI, XII and XVII (pages 7, 19 and 25) show data for tubes with a radial expansion ratio of 1.0, but the % dilation at the bursting pressure is 294, 275 and 252%, respectively. Therefore, the range of expansion of from 1.0 (greater than 1.0)-2.5 within the claimed range of “at least two times” is not supported since the specification does not provide support for a tube that has a radial expansion ratio of 1.0 that is expanded less than 2.5 times its original inner diameter.

In regard to claims 52 and 53, the claimed ranges are not supported in the specification as originally filed.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 42, 50 and 53 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claims 42 and 50, that which is intended to be recited by “radial expansion ratio of 1.0” cannot be ascertained since P_{max}, which is used to calculate the radial expansion ratio (page 7 of specification) cannot be determined on a balloon that has burst before reaching its P_{max} (see 35 U.S.C. 112, first paragraph rejection of claims 42 and 50 made of record in this Office Action).

Claim 53 fails to further limit the subject matter of claim 52 because the range “about 6 mm to about 30 mm” lies outside of the range “about 3 mm to about 6 mm” of claim 52.

Claim Rejections - 35 USC § 102

12. Claims 42, 50, 52 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Gore (US 3,962,153).

In regard to claim 42, Gore teaches a radially expandable tube consisting of extruded expanded polytetrafluoroethylene having a microstructure of nodes interconnected by fibrils (col. 14, lines 30-35 and col. 2, lines 52-55). Gore teaches that the tube is radially dilated to a diameter that is 2.8 times ($0.56/0.20 = 2.8$) the diameter of the tube prior to dilation (col. 14, line 49 to end of col. 14, see “Outside diameter” values for the unexpanded and expanded tubing in Table 8 in the last line of col. 14). While Gore teaches that the tube is sintered (col. 14, lines 55-57), the recitation “is sintered to contract said tube from said expanded diameter to a contracted diameter that is substantially the same as said original inner diameter” is a method limitation that has not been given patentable weight since the method of forming the tube is not germane to the issue of patentability of the tube itself. The claimed minimum ratio of expanded diameter/original diameter of the tube (i.e. “two times”) is relevant only insofar as the polytetrafluoroethylene of the prior art must be capable of expanding to the extent claimed by Applicant. The “said tube exhibiting a radial expansion ratio of 1.0...” recitation cannot be treated due to the indefiniteness of this recitation. See 35 U.S.C. 112, second paragraph rejection of claim 42 made of record in this Office Action.

In regard to claim 50, Gore teaches a highly crystalline porous polytetrafluoroethylene tube (col. 2, lines 52-63, col. 3, lines and col. 23, lines 22-32) consisting of extruded expanded

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polytetrafluoroethylene having a microstructure of nodes interconnected by fibrils (col. 14, lines 30-35 and col. 2, lines 52-55). Gore teaches that the tube is radially dilated to a diameter that is 2.8 times ($0.56/0.20 = 2.8$) the diameter of the tube prior to dilation (col. 14, line 49 to end of col. 14, see “Outside diameter” values for the unexpanded and expanded tubing in Table 8 in the last line of col. 14). The “the radial expansion ratio of the tube is about 1.0” recitation cannot be treated due to the indefiniteness of this recitation. See 35 U.S.C. 112, second paragraph rejection of claim 50 made of record in this Office Action.

In regard to claim 52, Gore teaches that the original inner diameter is 0.2-0.6 inches (col. 14, lines 50-54), which is 5.1-15.2 mm, a range that falls within Applicant’s claimed range of about 3mm to about 6 mm.

In regard to claim 53, Gore teaches that the original inner diameter is 0.2-0.6 inches (col. 14, lines 50-54), which is 5.1-15.2 mm, a range that falls within Applicant’s claimed range of about 6 mm to about 30 mm.

Claim Rejections - 35 USC § 103

13. Claims 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gore (US 3,962,153) in view of Gore (US 4,187,390).

Gore (‘153) teaches the tube as discussed above. Gore (‘153) teaches that the material of the tube has a relatively high permeability to nitrogen and that controlling the degree of expansion of the material of the tube and other processing conditions makes it possible to achieve any desired permeability within the range disclosed by Gore (‘153) (col. 5, lines 18-27).

Gore (‘153) fails to teach that the tube is radially dilated to at least three, four and five times the diameter of the tube prior to dilation.

Gore ('390), however, discloses a radially expandable tube consisting of extruded expanded polytetrafluoroethylene having a microstructure of nodes interconnected by fibrils (col. 2, lines 54-57 and col. 6, lines 45-50) where any desired permeability within the range disclosed by Gore ('390) can be achieved via control of the degree of expansion of the material of the tube and other processing conditions (col. 4, line 66-col. 5, line 7). Gore ('390) teaches that the tube is stretched to 5.5 times the original length (col. 6, line 62-col. 7, line 40) (presumably length, see claims 71-76 at col. 22, lines 8-26). Therefore, one of ordinary skill in the art would have recognized to have varied the degree of radial expansion of the tube of Gore ('153) to 5.5 times as taught by Gore ('390), and to at least any other value less than 5.5, in order to achieve the desired nitrogen permeability of the tube as taught by both Gore ('153) and Gore ('390).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the degree of radial expansion of the tube of Gore ('153) to 5.5 times as taught by Gore ('390), and to at least any other value less than 5.5, in order to achieve the desired nitrogen permeability of the tube as taught by both Gore ('153) and Gore ('390).

14. Claims 46-49 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gore (US 3,962,153) in view of Marin et al. (US 5,618,300).

Gore teaches the tube as discussed above. Gore fails to teach that the tube is attached to an expandable stent. Marin et al., however, disclose a graft-stent complex comprising an expandable polytetrafluoroethylene graft (item 46) that is sutured (therefore, attached) to a pair of expandable stents (items 48a and 48b) (col. 4, lines 43-65 and Fig. 1). Therefore, one of ordinary skill in the art would have recognized to have attached the pair of expandable stents of Marin et al. to the tube of Gore and to have used the resulting structure as the graft-stent complex

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of Marin et al. since it is notoriously well known to attach a pair of expandable stents to a expandable polytetrafluoroethylene tube to form a graft-stent complex as taught by Marin et al. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have attached the pair of expandable stents of Marin et al. to the tube of Gore and to have used the resulting structure as the graft-stent complex of Marin et al. since it is notoriously well known to attach a pair of expandable stents to a expandable polytetrafluoroethylene tube to form a graft-stent complex as taught by Marin et al.

Response to Arguments

15. Applicant's arguments presented on pages 4-5 of Amdt. A regarding the 35 U.S.C. 102 rejection of claim 42 have been fully considered but are not persuasive.

Applicant's intended definition of "radial expansion ratio" is addressed in the 35 U.S.C. 112 first and second paragraph rejections of claims 42 and 50 made of record in this Office Action. Applicant's arguments in the second full paragraph of page 5 of Amdt. A that Gore's method of forming the tube is "quite different" from Applicant's claimed method is not supported, and is not relevant since the method of forming the tube is not germane to the issue of patentability of the tube itself.

16. Applicant's arguments presented on pages 5-6 of Amdt. A regarding the 35 U.S.C. 103 rejections of claims 43-46 have been fully considered but are not persuasive. Applicant's arguments depend upon Applicant's arguments regarding the 35 U.S.C. 102 rejection of claim 42 which have been addressed above.

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Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is 571-272-1488. While the examiner sets his work schedule under the Increased Flexitime Policy, he can normally be reached on Monday-Friday from 8:45am to 5:15pm.

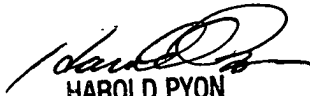
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is to 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Walter B. Aughenbaugh

02/06/06

WBA


HAROLD PYON
SUPERVISORY PATENT EXAMINER
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2/6/06